

**REMARKS**

**Statement of Substance of Interview**

As an initial matter, counsel would like to thank the Examiner for the courtesies extended during the telephone interview conducted December 1, 2009.

The Interview Summary attached to the Office Action mailed December 11, 2009 provides an accurate summary and statement of the substance of the interview.

**Response to Office Action of December 11, 2009**

Claims 1, 5, 6, 16, 20 and 21 are pending.

At page 3 of the Office Action, claims 1, 5-6, 16 and 20-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brantman (US 4,687,782) in view of Soop *et al.* (1988 J Appl Physiol 64(6): 2394-2399).

This rejection should be withdrawn because Brantman and Soop *et al.* do not disclose or render obvious the present invention, either alone or in combination.

Soop *et al.* is newly cited as teaching that adequate muscle carnitine levels are maintained during exercise and that carnitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions (p. 2399).

The Examiner considers that it would have been obvious to modify the teachings of Brantman and formulate a composition consisting of isoleucine, leucine, valine, glutamine, and a whey protein, *i.e.*, casein and administer said composition to an athlete, and that the motivation to exclude carnitine from said composition is suggested by Soop *et al.* which disclose that carnitine supplementation has no substantial effect on skeletal muscle metabolism.

In the Response under 37 C.F.R. § 1.111 filed October 5, 2009, Applicants explained that one of ordinary skill in the art would not readily have omitted carnitine from the composition of Brantman simply because it can be produced endogenously and it is present in the smallest amount out of all the components in the composition of Brantman, because Brantman adds exogenous carnitine to provide the best metabolic milieu for maximizing protein synthesis.

In response, the Examiner cites Soop *et al.* and states that it would be reasonable for one of ordinary skill to exclude carnitine from the composition of Brantman since Soop *et al.* discloses that carnitine supplementation has no substantial effect on skeletal muscle metabolism.

Applicants respectfully disagree.

Although Soop *et al.* teaches that carnitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions, Soop *et al.*'s study relates to the single use of carnitine and its effect on skeletal muscle metabolism under normal physiological conditions.

In contrast, Brantman teaches that the critical feature of his invention is the specific application of certain amino acids (carnitine, glutamine, isoleucine, leucine and valine) which exert beneficial effects on the metabolism (especially protein synthesis) of skeletal muscle (col. 1, lines 11-14 and 57-59).

Therefore, Soop *et al.* is not sufficient to provide motivation to one skilled in the art to omit carnitine from the composition of Brantman.

Further, Brantman recognizes that carnitine metabolism increases during exercise training (col. 3, lines 64-65) and teaches that "the present invention employs carnitine to optimize skeletal muscle function in relation to oxidation of fatty acids for calories; to the oxidation of

BAA for the effects summarized above; and to enhance the removal of toxic ammonia" (col. 4, lines 8-12).

That is, Brantman employs carnitine with other specific amino acids to promote muscle adaptation to strenuous exercise.

Accordingly, omission of carnitine from the composition of Brantman would render it unsatisfactory for its intended purpose; relevant law holds that if a proposed modification would render a prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Brantman expressly discloses that the intended purpose of the composition is to provide "a dietary supplement which provides the best metabolic milieu to permit and encourage protein synthesis in skeletal muscle and in liver ... [and that] the objects of the invention are realized by a careful selection of specific amino acids to be added to whole protein and other nutrients, so as to achieve a diet which is enriched with specific amino acids (carnitine, glutamine, isoleucine, leucine and valine), in order to maximize protein synthesis in skeletal muscle" (col. 4, lines 18-30). Therefore, by omitting carnitine, the composition is rendered unsatisfactory as a dietary supplement which provides the *best metabolic milieu* to permit and encourage protein synthesis in skeletal muscle and in liver, given that Brantman teaches carnitine as being critical for this purpose.

Furthermore, the composition defined in the claims of the instant application is patentable over Brantman from the fact that the claimed composition retains and improves the desired function even carnitine, which was an essential element of Brantman's composition, is omitted.

RESPONSE UNDER 37 C.F.R. § 1.111 AND STATEMENT OF SUBSTANCE OF  
INTERVIEW  
Application No.: 10/537,401

Attorney Docket No.: Q88294

The omission of an element and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966); MPEP 2144.04.

In view of the above, reconsideration and withdrawal of the §103(a) rejection based on Brantman in view of Soop *et al.* are respectfully requested.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: March 10, 2010